Vaccine Identification Standards Initiative (VISI)

Minutes of Conference Call
2000 June 7
11:00 am - 1:00 pm EDT

CALL PARTICIPANTS

Bruce Weniger (moderator)	National Immunization Program/CDC
Bindi Patel	National Immunization Program/CDC
Joanne Kim	American Academy of Pediatrics
Bill Purvis	Center for Biologics Evaluation and Research/FDA
Karen Chaitkin	Center for Biologics Evaluation and Research/FDA
Jane Gilbert	Chiron Corporation
Wikke Wallop	Health Canada
Paula Soper	Maryland Health Department
Katie Maher	Merck Vaccine Division
Jim Mundt	Merck Vaccine Division
Gina Butler-Galliera	SmithKline Beecham
Rick Schuessler	Symbol Technologies

SUMMARY

Introductions

Dr. Bruce Weniger welcomed all VISI participants and the participants identified themselves and their institutions in turn.

Discussion on Specific VISI components

Before the conference call, VISI participants had been urged to review the draft prototypes posted on the VISI web site and related information. These were discussed, as follows.

1. Re-cap of VISI Barcoding Subcommittee at UCC

- Dr. Weniger thanked the Uniform Code Council (UCC) representatives for inviting and hosting the VISI subcommittee meeting held at their headquarters in New Jersey on 27-April-2000 . Experts from both the software and hardware fields of barcoding, as well as vaccine manufacturers were brought together to help VISI determine what would be the best symbology(ies) and alternative options to specify for barcoding the vaccine cartons, vials, and peel-off stickers.

- Highlights of the meeting at UCC included:

  - The recommended "x" dimension for printing the Reduced Space Symbology (RSS) symbology is the largest x dimension capable of producing a symbol to fit the label window size, and should not be less than 6.7 mils (0.0067inch, 0.17 mm).

  - The minimum information for peel-off labels in human-readable form should include the NDC, the pick number or lot number, the expiration date, the vaccine type abbreviation, the vaccine manufacturer abbreviation, and the vaccine tradename.

  - The reduced-size composite barcode is not printable with current ink-jet technology.

2. Discussion of peel-off vaccine vial/syringe sticker prototypes and outer packaging barcode formatting

Peel-off Stickers

- Dr. Weniger referred to the sample peel-off stickers posted on the website that would be placed on vaccine vials, and to the sample barcodes on the outer carton or "secondary" packaging. Outer packaging barcode samples included: 1) a preprinted UPC-12 barcode for NDC only, 2) online-printed UCC/EAN Secondary Code 128 data for expiration date and lot number only (no NDC), and 3) online-printed UCC/EAN 128 barcode concatenating all data (NDC, expiration date, lot number), space permitting.

- While the call was in progress, Mr. Schuessler of Symbol Technologies scanned the sample prototypes and was able to read most, but not all, of the RSS prototypes created at the smallest 6.7 mils dimension, even from the web-downloaded conversions into Adobe® .pdf files from their native Codesoft™ originals. However, the function characters appeared to be missing from the embedded characters. Followup with UCC to ensure the prototypes are in conformance with UCC/EAN standards was called for.

- In discussing the one-dimensional RSS component, Mr. Schuessler suggested that the ***RSS Limited*** format was preferable over the ***RSS 14 stacked***, because its one-dimensional component did not require an extra scan for the adjacent layer. He said stacked symbologies were tough to read and in the future with software upgrades, even basic pen and wand scanners would be able to read the one-dimensional linear component of the ***RSS Limited*** format.

- Dr. Weniger asked VISI members if the minimum x-dimension of RSS labels on peel-off stickers be raised to 8.3 mils for better legibility. Mr. Schuessler indicated that the 6.7 mils scanned without problems, but suggested that vaccine manufacturers consider 7.5 mils as in the same general range but a better "minimum" x-dimension.

- Dr. Weniger brought up the issue of whether the entire label might peel-off, versus having a perforation with part of the label staying fixed to the vial. If so, then the RSS barcode and accompanying human-readable information might need to be printed in duplicate, so it

remains on the vial, too. Ms. Wallop stated that the Canadian immunization system recommends three stickers affixed to each vial, which include their DIN number (NDC equivalent), expiration date, and lot number.

Outer Package Barcodes

- Dr. Weniger will check with the UCC to determine whether the short-height preprinted UPC for outer packaging violates any standards. [Subsequently determined after the call that the UPC barcode -- used for retail products passing point-of-sale scanners -- should be supplanted on prescription-only vaccine cartons by the UCC/EAN 128 symbol, which is more up-to-date in conformance with growing international standardization of product identification.]

- VISI members agreed that the decision to place a full-size omni-directional barcode versus a reduced-height barcode on the outer packaging should be left to the manufacturer's discretion.

- Dr. Weniger will also check with the UCC regarding the suggested minimum 6mm height of reduced-height barcodes. Mr. Schuessler added that the height should be at least 15 percent of its width, to make it easier to use manual pen or wand scanners.

3. Discussion of *Vaccine Facts* information sidebars prototypes

- Dr. Weniger presented various vaccine information sidebar prototypes that Bindi had created and posted on the website for VISI members to review. He commented on his observation that each manufacturer had its own unique way to phrase the same kind of information occurring across different brands of vaccine.

- VISI members agreed that there is a lack of uniformity in the language used by different vaccine manufacturers to convey the same information, and that this language could be more standardized. Ms. Maher of Merck pointed out that any language used on such sidebars would need to be reviewed by their company's legal counsel.

- Dr. Weniger asked VISI members their thoughts about the term "Trace components" as the name for one of the Vaccine Facts fieldnames. Mr. Purvis of the FDA felt that this term was appropriate and suggested no changes to it.

4. Discussion of standardized vaccine abbreviations

- Dr. Weniger asked VISI members for comments on the standardized vaccine abbreviations.

- Ms. Wallop suggested that subscripting not be used because they are sometimes not available with some software. No other comments were offered.

5. Discussion of standardized manufacturer abbreviations

- Dr. Weniger asked VISI members for comments on the standardized manufacturer abbreviations. No comments were offered.

Next Steps

- The UCC will host another printing technology subcommittee meeting to be held on Thursday, 27 July 2000. This meeting will address the issue of high-speed online printing of Reduced Space Symbology (RSS)/Composite barcodes, as VISI specifies on peel-off stickers for vaccine vials and syringes. A respected expert in printing bar codes on manufacturer production lines, Rick Fox, will present his findings and advice about high-speed online printing. Any manufacturers which require label printing rates higher than 300 per minute for their production lines should contact UCC, as this rate is the challenge that Mr. Fox is being asked to address.

- Another conference call was set for Wednesday, July 26, at 11:00am. The following call information will be repeated and distributed via email closer to the event:

Call name: VISI	
Date:	Wednesday, 26 July 2000
Time:	11:00 - 12:00 am EDT (8-9 am PDT)
Phone no.:	[+1] 404-639-3277
Toll-free in US:	1-800-311-3437
Access Code:	###### [Deleted from website-posted document. Contact Bindi for access no.]

VISI Contact

Bindi I. Patel
Vaccine Development Fellow
VSDB/ National Immunization Program / CDC (MS E-61)
1600 Clifton Road
Atlanta, GA 30333
Tel: (404) 639-1861
Fax: (404) 639-8834
E-mail: bpatel@cdc.gov